



1 XAVIER BECERRA  
Attorney General of California  
2 E. A. JONES III  
Supervising Deputy Attorney General  
3 CLAUDIA RAMIREZ  
Deputy Attorney General  
4 State Bar No. 205340  
California Department of Justice  
5 300 South Spring Street, Suite 1702  
Los Angeles, California 90013  
6 Telephone: (213) 269-6482  
Facsimile: (213) 897-9395  
7 *Attorneys for Complainant*

8  
9 **BEFORE THE**  
**MEDICAL BOARD OF CALIFORNIA**  
10 **DEPARTMENT OF CONSUMER AFFAIRS**  
11 **STATE OF CALIFORNIA**

12  
13 In the Matter of the Accusation Against:

Case No. 800-2015-013951

14 Ellen B. Crowe, M.D.  
House Call Doctor Thousand Oaks, Inc.  
15 P.O. Box 4856  
Thousand Oaks, California 91359-1856

OAH No. 2018090379

**STIPULATED SETTLEMENT AND  
DISCIPLINARY ORDER**

16 Physician's and Surgeon's Certificate  
17 No. G 89024,

18 Respondent.

19  
20 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-  
21 entitled proceedings that the following matters are true:

22 **PARTIES**

23 1. Kimberly Kirchmeyer ("Complainant") is the Executive Director of the Medical  
24 Board of California ("Board"). She brought this action solely in her official capacity and is  
25 represented in this matter by Xavier Becerra, Attorney General of the State of California, by  
26 Claudia Ramirez, Deputy Attorney General.

27 2. Respondent Ellen B. Crowe, M.D. ("Respondent") is represented in this proceeding  
28 by attorney Michael Goch, Jr., whose address is: Law Offices of Michael Goch, A P.C., 5850

1 Canoga Avenue, Suite 400, Woodland Hills, California, 91367-6554.

2 3. On or about September 23, 2011, the Board issued Physician's and Surgeon's  
3 Certificate No. G 89024 to Respondent. That Certificate was in full force and effect at all times  
4 relevant to the charges brought in Accusation No. 800-2015-013951, and will expire on January  
5 31, 2021, unless renewed.

6 JURISDICTION

7 4. Accusation No. 800-2015-013951 was filed before the Board, and is currently  
8 pending against Respondent. The Accusation and all other statutorily required documents were  
9 properly served on Respondent on May 17, 2018. Respondent timely filed her Notice of Defense  
10 contesting the Accusation.

11 5. A copy of Accusation No. 800-2015-013951 is attached as Exhibit A and  
12 incorporated herein by reference.

13 ADVISEMENT AND WAIVERS

14 6. Respondent has carefully read, fully discussed with counsel, and understands the  
15 charges and allegations in Accusation No. 800-2015-013951. Respondent has also carefully read,  
16 fully discussed with counsel, and understands the effects of this Stipulated Settlement and  
17 Disciplinary Order.

18 7. Respondent is fully aware of her legal rights in this matter, including the right to a  
19 hearing on the charges and allegations in the Accusation; the right to confront and cross-examine  
20 the witnesses against her; the right to present evidence and to testify on her own behalf; the right  
21 to the issuance of subpoenas to compel the attendance of witnesses and the production of  
22 documents; the right to reconsideration and court review of an adverse decision; and all other  
23 rights accorded by the California Administrative Procedure Act and other applicable laws.

24 8. Respondent voluntarily, knowingly, and intelligently waives and gives up each and  
25 every right set forth above.

26 CULPABILITY

27 9. Respondent understands and agrees that the charges and allegations in Accusation  
28 No. 800-2015-013951, if proven at a hearing, constitute cause for imposing discipline upon her

1 Physician's and Surgeon's Certificate.

2 10. For the purpose of resolving the Accusation without the expense and uncertainty of  
3 further proceedings, Respondent agrees that, at a hearing, Complainant could establish a prima  
4 facie case for the charges in the First, Second, Third, and Fifth Causes for Discipline in the  
5 Accusation, and that Respondent hereby gives up her right to contest those charges.

6 11. Respondent agrees that if she ever petitions for early termination or modification of  
7 probation, or if the Board ever petitions for revocation of probation, all of the charges and  
8 allegations contained in Accusation No. 800-2015-013951 shall be deemed true, correct, and fully  
9 admitted by Respondent for purposes of that proceeding or any other licensing proceeding  
10 involving Respondent in the State of California.

11 12. Respondent agrees that her Physician's and Surgeon's Certificate is subject to  
12 discipline and she agrees to be bound by the Board's probationary terms as set forth in the  
13 Disciplinary Order below.

14 CIRCUMSTANCES IN MITIGATION

15 13. Respondent has never been the subject of any disciplinary action. She is admitting  
16 responsibility at an early stage in the proceedings.

17 CONTINGENCY

18 14. This stipulation shall be subject to approval by the Medical Board of California.  
19 Respondent understands and agrees that counsel for Complainant and the staff of the Medical  
20 Board of California may communicate directly with the Board regarding this stipulation and  
21 settlement, without notice to or participation by Respondent or her counsel. By signing the  
22 stipulation, Respondent understands and agrees that she may not withdraw her agreement or seek  
23 to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails  
24 to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary  
25 Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal  
26 action between the parties, and the Board shall not be disqualified from further action by having  
27 considered this matter.

28 15. The parties understand and agree that Portable Document Format (PDF) and facsimile

1 copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile  
2 signatures thereto, shall have the same force and effect as the originals.

3 16. In consideration of the foregoing admissions and stipulations, the parties agree that  
4 the Board may, without further notice or formal proceeding, issue and enter the following  
5 Disciplinary Order:

6 **DISCIPLINARY ORDER**

7 IT IS HEREBY ORDERED that Physician's and Surgeon's Certificate No. G 89024 issued  
8 to Respondent Ellen B. Crowe, M.D. is revoked. However, the revocation is stayed and  
9 Respondent is placed on probation for three (3) years on the following terms and conditions.

10 1. **EDUCATION COURSE.** Within 60 calendar days of the effective date of this  
11 Decision, Respondent shall enroll in a four-hour, in-person course specific to a physician's  
12 supervision of unlicensed personnel (i.e., medical assistants and office/practice/business  
13 managers), including the delegation of medical tasks to unlicensed personnel, and the scope of  
14 practice of such unlicensed personnel, approved in advance by the Board or its designee.  
15 Respondent shall provide the approved course provider with any information and documents that  
16 the approved course provider may deem pertinent. Respondent shall participate in and  
17 successfully complete the classroom component of the course not later than six (6) months after  
18 Respondent's initial enrollment. Respondent shall successfully complete any other component of  
19 the course within one (1) year of enrollment. The course shall be at Respondent's expense and  
20 shall be in addition to the Continuing Medical Education (CME) requirements for renewal of  
21 licensure.

22 A course that is specific to a physician's supervision of unlicensed personnel, as described  
23 above, taken after the acts that gave rise to the charges in the Accusation, but prior to the effective  
24 date of the Decision may, in the sole discretion of the Board or its designee, be accepted towards  
25 the fulfillment of this condition if the course would have been approved by the Board or its  
26 designee had the course been taken after the effective date of this Decision.

27 Respondent shall submit a certification of successful completion to the Board or its  
28 designee not later than 15 calendar days after successfully completing the course, or not later than

1 15 calendar days after the effective date of the Decision, whichever is later.

2 2. MEDICAL RECORD KEEPING COURSE. Within 60 calendar days of the effective  
3 date of this Decision, Respondent shall enroll in a course in medical record keeping approved in  
4 advance by the Board or its designee. Respondent shall provide the approved course provider  
5 with any information and documents that the approved course provider may deem pertinent.  
6 Respondent shall participate in and successfully complete the classroom component of the course  
7 not later than six (6) months after Respondent's initial enrollment. Respondent shall successfully  
8 complete any other component of the course within one (1) year of enrollment. The medical  
9 record keeping course shall be at Respondent's expense and shall be in addition to the Continuing  
10 Medical Education (CME) requirements for renewal of licensure.

11 A medical record keeping course taken after the acts that gave rise to the charges in the  
12 Accusation, but prior to the effective date of the Decision may, in the sole discretion of the Board  
13 or its designee, be accepted towards the fulfillment of this condition if the course would have  
14 been approved by the Board or its designee had the course been taken after the effective date of  
15 this Decision.

16 Respondent shall submit a certification of successful completion to the Board or its  
17 designee not later than 15 calendar days after successfully completing the course, or not later than  
18 15 calendar days after the effective date of the Decision, whichever is later.

19 3. PROFESSIONALISM PROGRAM (ETHICS COURSE). Within 60 calendar days of  
20 the effective date of this Decision, Respondent shall enroll in a professionalism program, that  
21 meets the requirements of Title 16, California Code of Regulations (CCR) section 1358.1.  
22 Respondent shall participate in and successfully complete that program. Respondent shall  
23 provide any information and documents that the program may deem pertinent. Respondent shall  
24 successfully complete the classroom component of the program not later than six (6) months after  
25 Respondent's initial enrollment, and the longitudinal component of the program not later than the  
26 time specified by the program, but no later than one (1) year after attending the classroom  
27 component. The professionalism program shall be at Respondent's expense and shall be in  
28 addition to the Continuing Medical Education (CME) requirements for renewal of licensure.

1 A professionalism program taken after the acts that gave rise to the charges in the  
2 Accusation, but prior to the effective date of the Decision may, in the sole discretion of the Board  
3 or its designee, be accepted towards the fulfillment of this condition if the program would have  
4 been approved by the Board or its designee had the program been taken after the effective date of  
5 this Decision.

6 Respondent shall submit a certification of successful completion to the Board or its  
7 designee not later than 15 calendar days after successfully completing the program or not later  
8 than 15 calendar days after the effective date of the Decision, whichever is later.

9 4. NOTIFICATION. Within seven (7) days of the effective date of this Decision, the  
10 Respondent shall provide a true copy of this Decision and Accusation to the Chief of Staff or the  
11 Chief Executive Officer at every hospital where privileges or membership are extended to  
12 Respondent, at any other facility where Respondent engages in the practice of medicine,  
13 including all physician and locum tenens registries or other similar agencies, and to the Chief  
14 Executive Officer at every insurance carrier which extends malpractice insurance coverage to  
15 Respondent. Respondent shall submit proof of compliance to the Board or its designee within 15  
16 calendar days.

17 This condition shall apply to any change(s) in hospitals, other facilities or insurance carrier.

18 5. SUPERVISION OF PHYSICIAN ASSISTANTS AND ADVANCED PRACTICE  
19 NURSES. During probation, Respondent is prohibited from supervising physician assistants and  
20 advanced practice nurses in any solo or group private practice. Respondent is permitted to  
21 supervise physician assistants and advanced practice nurses at any hospital where she maintains  
22 privileges or membership.

23 6. OBEY ALL LAWS. Respondent shall obey all federal, state and local laws, all rules  
24 governing the practice of medicine in California and remain in full compliance with any court  
25 ordered criminal probation, payments, and other orders.

26 7. QUARTERLY DECLARATIONS. Respondent shall submit quarterly declarations  
27 under penalty of perjury on forms provided by the Board, stating whether there has been  
28 compliance with all the conditions of probation.

1 Respondent shall submit quarterly declarations not later than 10 calendar days after the end  
2 of the preceding quarter.

3 8. GENERAL PROBATION REQUIREMENTS.

4 Compliance with Probation Unit

5 Respondent shall comply with the Board's probation unit.

6 Address Changes

7 Respondent shall, at all times, keep the Board informed of Respondent's business and  
8 residence addresses, email address (if available), and telephone number. Changes of such  
9 addresses shall be immediately communicated in writing to the Board or its designee. Under no  
10 circumstances shall a post office box serve as an address of record, except as allowed by Business  
11 and Professions Code section 2021(b).

12 Place of Practice

13 Respondent shall not engage in the practice of medicine in Respondent's or patient's place  
14 of residence, unless the patient resides in a skilled nursing facility or other similar licensed  
15 facility, or unless the patients' medical records are maintained in a location where they are  
16 available for inspection upon request by the Board or its designee.

17 License Renewal

18 Respondent shall maintain a current and renewed California physician's and surgeon's  
19 license.

20 Travel or Residence Outside California

21 Respondent shall immediately inform the Board or its designee, in writing, of travel to any  
22 areas outside the jurisdiction of California which lasts, or is contemplated to last, more than thirty  
23 (30) calendar days.

24 In the event Respondent should leave the State of California to reside or to practice,  
25 Respondent shall notify the Board or its designee in writing 30 calendar days prior to the dates of  
26 departure and return.

27 9. INTERVIEW WITH THE BOARD OR ITS DESIGNEE. Respondent shall be  
28 available in person upon request for interviews either at Respondent's place of business or at the

1 probation unit office, with or without prior notice throughout the term of probation.

2 10. NON-PRACTICE WHILE ON PROBATION. Respondent shall notify the Board or  
3 its designee in writing within 15 calendar days of any periods of non-practice lasting more than  
4 30 calendar days and within 15 calendar days of Respondent's return to practice. Non-practice is  
5 defined as any period of time Respondent is not practicing medicine as defined in Business and  
6 Professions Code sections 2051 and 2052 for at least 40 hours in a calendar month in direct  
7 patient care, clinical activity or teaching, or other activity as approved by the Board. If  
8 Respondent resides in California and is considered to be in non-practice, Respondent shall  
9 comply with all terms and conditions of probation. All time spent in an intensive training  
10 program which has been approved by the Board or its designee shall not be considered non-  
11 practice and does not relieve Respondent from complying with all the terms and conditions of  
12 probation. Practicing medicine in another state of the United States or Federal jurisdiction while  
13 on probation with the medical licensing authority of that state or jurisdiction shall not be  
14 considered non-practice. A Board-ordered suspension of practice shall not be considered as a  
15 period of non-practice.

16 In the event Respondent's period of non-practice while on probation exceeds 18 calendar  
17 months, Respondent shall successfully complete the Federation of State Medical Boards's Special  
18 Purpose Examination, or, at the Board's discretion, a clinical competence assessment program  
19 that meets the criteria of Condition 18 of the current version of the Board's "Manual of Model  
20 Disciplinary Orders and Disciplinary Guidelines" prior to resuming the practice of medicine.

21 Respondent's period of non-practice while on probation shall not exceed two (2) years.

22 Periods of non-practice will not apply to the reduction of the probationary term.

23 Periods of non-practice for a Respondent residing outside of California will relieve  
24 Respondent of the responsibility to comply with the probationary terms and conditions with the  
25 exception of this condition and the following terms and conditions of probation: Obey All Laws;  
26 General Probation Requirements; Quarterly Declarations; Abstain from the Use of Alcohol and/or  
27 Controlled Substances; and Biological Fluid Testing.

28 11. COMPLETION OF PROBATION. Respondent shall comply with all financial

obligations (e.g., restitution, probation costs) not later than 120 calendar days prior to the completion of probation. Upon successful completion of probation, Respondent's certificate shall be fully restored.

12. VIOLATION OF PROBATION. Failure to fully comply with any term or condition of probation is a violation of probation. If Respondent violates probation in any respect, the Board, after giving Respondent notice and the opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If an Accusation, or Petition to Revoke Probation, or an Interim Suspension Order is filed against Respondent during probation, the Board shall have continuing jurisdiction until the matter is final, and the period of probation shall be extended until the matter is final.

13. LICENSE SURRENDER. Following the effective date of this Decision, if Respondent ceases practicing due to retirement or health reasons or is otherwise unable to satisfy the terms and conditions of probation, Respondent may request to surrender his or her license. The Board reserves the right to evaluate Respondent's request and to exercise its discretion in determining whether or not to grant the request, or to take any other action deemed appropriate and reasonable under the circumstances. Upon formal acceptance of the surrender, Respondent shall within 15 calendar days deliver Respondent's wallet and wall certificate to the Board or its designee and Respondent shall no longer practice medicine. Respondent will no longer be subject to the terms and conditions of probation. If Respondent re-applies for a medical license, the application shall be treated as a petition for reinstatement of a revoked certificate.


14. PROBATION MONITORING COSTS. Respondent shall pay the costs associated with probation monitoring each and every year of probation, as designated by the Board, which may be adjusted on an annual basis. Such costs shall be payable to the Medical Board of California and delivered to the Board or its designee no later than January 31 of each calendar year.

#### ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Michael Goch, Jr., Esq. I understand the stipulation and the effect

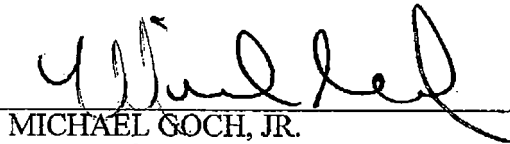
1 it will have on my Physician's and Surgeon's Certificate. I enter into this Stipulated Settlement  
2 and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the  
3 Decision and Order of the Medical Board of California.

4  
5  
6  
7 DATED: 3/21/19

  
ELLEN B. CROWE, M.D.  
Respondent

10 I have read and fully discussed with Respondent Ellen B. Crowe, M.D. the terms and  
11 conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order.  
12 I approve its form and content.

13  
14  
15  
16 DATED: 03/22/19

  
MICHAEL GOCH, JR.  
Attorney for Respondent

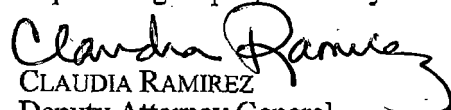
18  
19 ENDORSEMENT

20 The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully  
21 submitted for consideration by the Medical Board of California.

22 Dated: 3/22/19

Respectfully submitted,

23 XAVIER BECERRA  
24 Attorney General of California  
25 E. A. JONES III  
Supervising Deputy Attorney General

  
26 CLAUDIA RAMIREZ  
27 Deputy Attorney General  
Attorneys for Complainant

28 LA2018501123/53282134.docx

**Exhibit A**

**Accusation No. 800-2015-013951**

1 XAVIER BECERRA  
Attorney General of California  
2 E. A. JONES III  
Supervising Deputy Attorney General  
3 CLAUDIA RAMIREZ  
Deputy Attorney General  
4 State Bar No. 205340  
California Department of Justice  
5 300 South Spring Street, Suite 1702  
Los Angeles, CA 90013  
6 Telephone: (213) 269-6482  
Facsimile: (213) 897-9395  
7 *Attorneys for Complainant*

8 **BEFORE THE**  
9 **MEDICAL BOARD OF CALIFORNIA**  
10 **DEPARTMENT OF CONSUMER AFFAIRS**  
11 **STATE OF CALIFORNIA**

11 In the Matter of the Accusation Against:

Case No. 800-2015-013951

12 Ellen B. Crowe, M.D.  
House Call Doctor Thousand Oaks, Inc.  
13 P.O. Box 4856  
Thousand Oaks, California 91359-1856

**ACCUSATION**

14 Physician's and Surgeon's Certificate  
15 No. G 89024,

16 Respondent.

17  
18 Complainant alleges:

19 **PARTIES**

20 1. Kimberly Kirchmeyer ("Complainant") brings this Accusation solely in her official  
21 capacity as the Executive Director of the Medical Board of California, Department of Consumer  
22 Affairs ("Board").

23 2. On or about September 23, 2011, the Medical Board issued Physician's and  
24 Surgeon's Certificate Number G 89024 to Ellen B. Crowe, M.D. ("Respondent"). That certificate  
25 was in full force and effect at all times relevant to the charges brought herein and will expire on  
26 January 31, 2019, unless renewed.

27 **JURISDICTION**

28 3. This Accusation is brought before the Board, under the authority of the following

1 laws. All section references are to the Business and Professions Code ("Code") unless otherwise  
2 indicated.

### 3 BUSINESS AND PROFESSIONS CODE

4 4. Section 2004, subdivisions (a) through (d), of the Code states:

5 "The board shall have the responsibility for the following:

6 "(a) The enforcement of the disciplinary and criminal provisions of the Medical Practice  
7 Act.

8 "(b) The administration and hearing of disciplinary actions.

9 "(c) Carrying out disciplinary actions appropriate to findings made by a panel or an  
10 administrative law judge.

11 "(d) Suspending, revoking, or otherwise limiting certificates after the conclusion of  
12 disciplinary actions.

13 "..."

14 5. Section 2227 of the Code provides that a licensee who is found guilty under the  
15 Medical Practice Act may have his or her license revoked, suspended for a period not to exceed  
16 one year, placed on probation and required to pay the costs of probation monitoring, or such other  
17 action taken in relation to discipline as the Board deems proper.

18 6. Section 2234 of the Code states:

19 "The board shall take action against any licensee who is charged with unprofessional  
20 conduct. In addition to other provisions of this article, unprofessional conduct includes, but is not  
21 limited to, the following:

22 "(a) Violating or attempting to violate, directly or indirectly, assisting in or abetting the  
23 violation of, or conspiring to violate any provision of this chapter.

24 "(b) Gross negligence.

25 "(c) Repeated negligent acts. To be repeated, there must be two or more negligent acts or  
26 omissions. An initial negligent act or omission followed by a separate and distinct departure from  
27 the applicable standard of care shall constitute repeated negligent acts.

28 "(1) An initial negligent diagnosis followed by an act or omission medically appropriate for

1 that negligent diagnosis of the patient shall constitute a single negligent act.

2 “(2) When the standard of care requires a change in the diagnosis, act, or omission that  
3 constitutes the negligent act described in paragraph (1), including, but not limited to, a  
4 reevaluation of the diagnosis or a change in treatment, and the licensee's conduct departs from the  
5 applicable standard of care, each departure constitutes a separate and distinct breach of the  
6 standard of care.

7 “(d) Incompetence.

8 “(e) The commission of any act involving dishonesty or corruption which is substantially  
9 related to the qualifications, functions, or duties of a physician and surgeon.

10 “(f) Any action or conduct which would have warranted the denial of a certificate.

11 “(g) The practice of medicine from this state into another state or country without meeting  
12 the legal requirements of that state or country for the practice of medicine. Section 2314 shall not  
13 apply to this subdivision. This subdivision shall become operative upon the implementation of  
14 the proposed registration program described in Section 2052.5.

15 “(h) The repeated failure by a certificate holder, in the absence of good cause, to attend and  
16 participate in an interview by the board. This subdivision shall only apply to a certificate holder  
17 who is the subject of an investigation by the board.”

18 7. Section 2051 of the Code states:

19 “The physician's and surgeon's certificate authorizes the holder to use drugs or devices in  
20 or upon human beings and to sever or penetrate the tissues of human beings and to use any and all  
21 other methods in the treatment of diseases, injuries, deformities, and other physical and mental  
22 conditions.”

23 8. Section 2052 of the Code states:

24 “(a) Notwithstanding Section 146, any person who practices or attempts to practice, or who  
25 advertises or holds himself or herself out as practicing, any system or mode of treating the sick or  
26 afflicted in this state, or who diagnoses, treats, operates for, or prescribes for any ailment,  
27 blemish, deformity, disease, disfigurement, disorder, injury, or other physical or mental condition  
28 of any person, without having at the time of so doing a valid, unrevoked, or unsuspended

1 certificate as provided in this chapter or without being authorized to perform the act pursuant to a  
2 certificate obtained in accordance with some other provision of law is guilty of a public offense,  
3 punishable by a fine not exceeding ten thousand dollars (\$10,000), by imprisonment pursuant to  
4 subdivision (h) of Section 1170 of the Penal Code, by imprisonment in a county jail not exceeding  
5 one year, or by both the fine and either imprisonment.

6 “(b) Any person who conspires with or aids or abets another to commit any act described in  
7 subdivision (a) is guilty of a public offense, subject to the punishment described in that  
8 subdivision.

9 “(c) The remedy provided in this section shall not preclude any other remedy provided by  
10 law.”

11 9. Section 2053.5 of the Code states:

12 “(a) Notwithstanding any other provision of law, a person who complies with the  
13 requirements of Section 2053.6 shall not be in violation of Section 2051 or 2052 unless that  
14 person does any of the following:

15 “...”

16 “(3) Prescribes or administers legend drugs or controlled substances to another person.”

17 10. Section 2264 of the Code states:

18 “The employing, directly or indirectly, the aiding, or the abetting of any unlicensed person  
19 or any suspended, revoked, or unlicensed practitioner to engage in the practice of medicine or any  
20 other mode of treating the sick or afflicted which requires a license to practice constitutes  
21 unprofessional conduct.”

22 11. Section 2069 of the Code states:

23 “(a)(1) Notwithstanding any other law, a medical assistant may administer medication only  
24 by intradermal, subcutaneous, or intramuscular injections and perform skin tests and additional  
25 technical supportive services upon the specific authorization and supervision of a licensed  
26 physician and surgeon or a licensed podiatrist. A medical assistant may also perform all these  
27 tasks and services upon the specific authorization of a physician assistant, a nurse practitioner, or  
28 a certified nurse-midwife.

1       “(2) The supervising physician and surgeon may, at his or her discretion, in consultation  
2 with the nurse practitioner, certified nurse-midwife, or physician assistant, provide written  
3 instructions to be followed by a medical assistant in the performance of tasks or supportive  
4 services. These written instructions may provide that the supervisory function for the medical  
5 assistant for these tasks or supportive services may be delegated to the nurse practitioner, certified  
6 nurse-midwife, or physician assistant within the standardized procedures or protocol, and that  
7 tasks may be performed when the supervising physician and surgeon is not onsite, if either of the  
8 following apply:

9       “(A) The nurse practitioner or certified nurse-midwife is functioning pursuant to  
10 standardized procedures, as defined by Section 2725, or protocol. The standardized procedures or  
11 protocol, including instructions for specific authorizations, shall be developed and approved by  
12 the supervising physician and surgeon and the nurse practitioner or certified nurse-midwife.

13       “(B) The physician assistant is functioning pursuant to regulated services defined in Section  
14 3502, including instructions for specific authorizations, and is approved to do so by the  
15 supervising physician and surgeon.

16       “(b) As used in this section and Sections 2070 and 2071, the following definitions apply:

17       “(1) ‘Medical assistant’ means a person who may be unlicensed, who performs basic  
18 administrative, clerical, and technical supportive services in compliance with this section and  
19 Section 2070 for a licensed physician and surgeon or a licensed podiatrist, or group thereof, for a  
20 medical or podiatry corporation, for a physician assistant, a nurse practitioner, or a certified nurse-  
21 midwife as provided in subdivision (a), or for a health care service plan, who is at least 18 years  
22 of age, and who has had at least the minimum amount of hours of appropriate training pursuant to  
23 standards established by the board. The medical assistant shall be issued a certificate by the  
24 training institution or instructor indicating satisfactory completion of the required training. A  
25 copy of the certificate shall be retained as a record by each employer of the medical assistant.

26       “(2) ‘Specific authorization’ means a specific written order prepared by the supervising  
27 physician and surgeon or the supervising podiatrist, or the physician assistant, the nurse  
28 practitioner, or the certified nurse-midwife as provided in subdivision (a), authorizing the

1 procedures to be performed on a patient, which shall be placed in the patient's medical record, or a  
2 standing order prepared by the supervising physician and surgeon or the supervising podiatrist, or  
3 the physician assistant, the nurse practitioner, or the certified nurse-midwife as provided in  
4 subdivision (a), authorizing the procedures to be performed, the duration of which shall be  
5 consistent with accepted medical practice. A notation of the standing order shall be placed on the  
6 patient's medical record.

7 “(3) ‘Supervision’ means the supervision of procedures authorized by this section by the  
8 following practitioners, within the scope of their respective practices, who shall be physically  
9 present in the treatment facility during the performance of those procedures:

10 “(A) A licensed physician and surgeon.

11 “(B) A licensed podiatrist.

12 “(C) A physician assistant, nurse practitioner, or certified nurse-midwife as provided in  
13 subdivision (a).

14 “(4) ‘Technical supportive services’ means simple routine medical tasks and procedures that  
15 may be safely performed by a medical assistant who has limited training and who functions under  
16 the supervision of a licensed physician and surgeon or a licensed podiatrist, or a physician  
17 assistant, a nurse practitioner, or a certified nurse-midwife as provided in subdivision (a).

18 “(c) Nothing in this section shall be construed as authorizing any of the following:

19 “(1) The licensure of medical assistants.

20 “(2) The administration of local anesthetic agents by a medical assistant.

21 “(3) The board to adopt any regulations that violate the prohibitions on diagnosis or  
22 treatment in Section 2052.

23 “(4) A medical assistant to perform any clinical laboratory test or examination for which he  
24 or she is not authorized by Chapter 3 (commencing with Section 1200).

25 “(5) A nurse practitioner, certified nurse-midwife, or physician assistant to be a laboratory  
26 director of a clinical laboratory, as those terms are defined in paragraph (8) of subdivision (a) of  
27 Section 1206 and subdivision (a) of Section 1209.

28 “(d) A nurse practitioner, certified nurse-midwife, or physician assistant shall not authorize

1 a medical assistant to perform any clinical laboratory test or examination for which the medical  
2 assistant is not authorized by Chapter 3 (commencing with Section 1200). A violation of this  
3 subdivision constitutes unprofessional conduct.

4 “(e) Notwithstanding any other law, a medical assistant shall not be employed for inpatient  
5 care in a licensed general acute care hospital, as defined in subdivision (a) of Section 1250 of the  
6 Health and Safety Code.”

7 12. Section 2238 of the Code states:

8 “A violation of any federal statute or federal regulation or any of the statutes or regulations  
9 of this state regulating dangerous drugs or controlled substances constitutes unprofessional  
10 conduct.”

11 13. Section 2266 of the Code states:

12 “The failure of a physician and surgeon to maintain adequate and accurate records relating  
13 to the provision of services to their patients constitutes unprofessional conduct.”

14 14. Section 4016 of the Code states:

15 “‘Administer’ means the direct application of a drug or device to the body of a patient or  
16 research subject by injection, inhalation, ingestion, or other means.”

17 15. Section 4024 of the Code states:

18 “(a) Except as provided in subdivision (b), ‘dispense’ means the furnishing of drugs or  
19 devices upon a prescription from a physician, dentist, optometrist, podiatrist, veterinarian, or  
20 naturopathic doctor pursuant to Section 3640.7, or upon an order to furnish drugs or transmit a  
21 prescription from a certified nurse-midwife, nurse practitioner, physician assistant, naturopathic  
22 doctor pursuant to Section 3640.5, or pharmacist acting within the scope of his or her practice.

23 “(b) ‘Dispense’ also means and refers to the furnishing of drugs or devices directly to a  
24 patient by a physician, dentist, optometrist, podiatrist, or veterinarian, or by a certified nurse-  
25 midwife, nurse practitioner, naturopathic doctor, or physician assistant acting within the scope of  
26 his or her practice.”

27 16. Section 4026 of the Code states:

28 “‘Furnish’ means to supply by any means, by sale or otherwise.”

1       17. Section 4080 of the Code states:

2       “All stock of any dangerous drug or dangerous device or of shipments through a customs  
3 broker or carrier shall be, at all times during business hours, open to inspection by authorized  
4 officers of the law.”

5       18. Section 4081, subdivision (a), of the Code states:

6       “(a) All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of  
7 dangerous drugs or dangerous devices shall be at all times during business hours open to  
8 inspection by authorized officers of the law, and shall be preserved for at least three years from  
9 the date of making. A current inventory shall be kept by every manufacturer, wholesaler, third-  
10 party logistics provider, pharmacy, veterinary food-animal drug retailer, outsourcing facility,  
11 physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment  
12 holding a currently valid and unrevoked certificate, license, permit, registration, or exemption  
13 under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4  
14 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who  
15 maintains a stock of dangerous drugs or dangerous devices.”

16       19. Section 4170 of the Code states:

17       “(a) No prescriber shall dispense drugs or dangerous devices to patients in his or her office  
18 or place of practice unless all of the following conditions are met:

19       “(1) The dangerous drugs or dangerous devices are dispensed to the prescriber's own  
20 patient, and the drugs or dangerous devices are not furnished by a nurse or physician attendant.

21       “(2) The dangerous drugs or dangerous devices are necessary in the treatment of the  
22 condition for which the prescriber is attending the patient.

23       “(3) The prescriber does not keep a pharmacy, open shop, or drugstore, advertised or  
24 otherwise, for the retailing of dangerous drugs, dangerous devices, or poisons.

25       “(4) The prescriber fulfills all of the labeling requirements imposed upon pharmacists by  
26 Section 4076, all of the recordkeeping requirements of this chapter, and all of the packaging  
27 requirements of good pharmaceutical practice, including the use of childproof containers.

28       “(5) The prescriber does not use a dispensing device unless he or she personally owns the

1 device and the contents of the device, and personally dispenses the dangerous drugs or dangerous  
2 devices to the patient packaged, labeled, and recorded in accordance with paragraph (4).

3 “(6) The prescriber, prior to dispensing, offers to give a written prescription to the patient  
4 that the patient may elect to have filled by the prescriber or by any pharmacy.

5 “(7) The prescriber provides the patient with written disclosure that the patient has a choice  
6 between obtaining the prescription from the dispensing prescriber or obtaining the prescription at  
7 a pharmacy of the patient's choice.

8 “(8) A certified nurse-midwife who functions pursuant to a standardized procedure or  
9 protocol described in Section 2746.51, a nurse practitioner who functions pursuant to a  
10 standardized procedure described in Section 2836.1, or protocol, a physician assistant who  
11 functions pursuant to Section 3502.1, or a naturopathic doctor who functions pursuant to Section  
12 3640.5, may hand to a patient of the supervising physician and surgeon a properly labeled  
13 prescription drug prepackaged by a physician and surgeon, a manufacturer as defined in this  
14 chapter, or a pharmacist.

15 “(b) The Medical Board of California, the State Board of Optometry, the Bureau of  
16 Naturopathic Medicine, the Dental Board of California, the Osteopathic Medical Board of  
17 California, the Board of Registered Nursing, the Veterinary Medical Board, and the Physician  
18 Assistant Committee shall have authority with the California State Board of Pharmacy to ensure  
19 compliance with this section, and those boards are specifically charged with the enforcement of  
20 this chapter with respect to their respective licensees.

21 “(c) ‘Prescriber,’ as used in this section, means a person, who holds a physician's and  
22 surgeon's certificate, a license to practice optometry, a license to practice naturopathic medicine, a  
23 license to practice dentistry, a license to practice veterinary medicine, or a certificate to practice  
24 podiatry, and who is duly registered by the Medical Board of California, the State Board of  
25 Optometry, the Bureau of Naturopathic Medicine, the Dental Board of California, the Veterinary  
26 Medical Board, or the Board of Osteopathic Examiners of this state.”

27 20. Section 4172 of the Code states:

28 “A prescriber who dispenses drugs pursuant to Section 4170 shall store all drugs to be

1 dispensed in an area that is secure. The Medical Board of California shall, by regulation, define  
2 the term 'secure' for purposes of this section."

3 21. Section 4119 of the Code states:

4 "(a) Notwithstanding any other provision of law, a pharmacy may furnish a dangerous drug  
5 or dangerous device to a licensed health care facility for storage in a secured emergency  
6 pharmaceutical supplies container maintained within the facility in accordance with facility  
7 regulations of the State Department of Public Health set forth in Title 22 of the California Code of  
8 Regulations and the requirements set forth in Section 1261.5 of the Health and Safety Code.  
9 These emergency supplies shall be approved by the facility's patient care policy committee or  
10 pharmaceutical service committee and shall be readily available to each nursing station. Section  
11 1261.5 of the Health and Safety Code limits the number of oral dosage form or suppository form  
12 drugs in these emergency supplies to 24.

13 "(b) Notwithstanding any other provision of law, a pharmacy may furnish a dangerous drug  
14 or a dangerous device to an approved service provider within an emergency medical services  
15 system for storage in a secured emergency pharmaceutical supplies container, in accordance with  
16 the policies and procedures of the local emergency medical services agency, if all of the following  
17 are met:

18 "(1) The dangerous drug or dangerous device is furnished exclusively for use in conjunction  
19 with services provided in an ambulance, or other approved emergency medical services service  
20 provider, that provides prehospital emergency medical services.

21 "(2) The requested dangerous drug or dangerous device is within the licensed or certified  
22 emergency medical technician's scope of practice as established by the Emergency Medical  
23 Services Authority and set forth in Title 22 of the California Code of Regulations.

24 "(3) The approved service provider within an emergency medical services system provides a  
25 written request that specifies the name and quantity of dangerous drugs or dangerous devices.

26 "(4) The approved emergency medical services provider administers dangerous drugs and  
27 dangerous devices in accordance with the policies and procedures of the local emergency medical  
28 services agency.

1       “(5) The approved emergency medical services provider documents, stores, and restocks  
2 dangerous drugs and dangerous devices in accordance with the policies and procedures of the  
3 local emergency medical services agency.

4       “Records of each request by, and dangerous drugs or dangerous devices furnished to, an  
5 approved service provider within an emergency medical services system, shall be maintained by  
6 both the approved service provider and the dispensing pharmacy for a period of at least three  
7 years.

8       “The furnishing of controlled substances to an approved emergency medical services  
9 provider shall be in accordance with the California Uniform Controlled Substances Act.”

#### 10                                   **HEALTH AND SAFETY CODE**

11       22. Health and Safety Code section 11002 states:

12       “‘Administer’ means the direct application of a controlled substance, whether by injection,  
13 inhalation, ingestion, or any other means, to the body of a patient for his immediate needs or to  
14 the body of a research subject by any of the following:

15       “(a) A practitioner or, in his presence, by his authorized agent.

16       “(b) The patient or research subject at the direction and in the presence of the practitioner.”

17       23. Health and Safety Code section 11010 states:

18       “‘Dispense’ means to deliver a controlled substance to an ultimate user or research subject  
19 by or pursuant to the lawful order of a practitioner, including the prescribing, furnishing,  
20 packaging, labeling, or compounding necessary to prepare the substance for that delivery.”

21       24. Health and Safety Code section 11016 states:

22       “‘Furnish’ has the same meaning as provided in Section 4048.5 of the Business and  
23 Professions Code.”

24       25. Health and Safety Code section 11027, subdivision (a), states:

25       “(a) ‘Prescription’ means an oral order or electronic transmission prescription for a  
26 controlled substance given individually for the person(s) for whom prescribed, directly from the  
27 prescriber to the furnisher or indirectly by means of a written order of the prescriber.”

28       26. Health and Safety Code section 11153, subdivision (a), states:

1       “(a) A prescription for a controlled substance shall only be issued for a legitimate medical  
2       purpose by an individual practitioner acting in the usual course of his or her professional practice.  
3       The responsibility for the proper prescribing and dispensing of controlled substances is upon the  
4       prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the  
5       prescription. Except as authorized by this division, the following are not legal prescriptions: (1)  
6       an order purporting to be a prescription which is issued not in the usual course of professional  
7       treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of  
8       controlled substances, which is issued not in the course of professional treatment or as part of an  
9       authorized narcotic treatment program, for the purpose of providing the user with controlled  
10      substances, sufficient to keep him or her comfortable by maintaining customary use.

11       27. Health and Safety Code section 11158 states:

12       “(a) Except as provided in Section 11159 or in subdivision (b) of this section, no controlled  
13      substance classified in Schedule II shall be dispensed without a prescription meeting the  
14      requirements of this chapter. Except as provided in Section 11159 or when dispensed directly to  
15      an ultimate user by a practitioner, other than a pharmacist or pharmacy, no controlled substance  
16      classified in Schedule III, IV, or V may be dispensed without a prescription meeting the  
17      requirements of this chapter.

18       “(b) A practitioner specified in Section 11150 may dispense directly to an ultimate user a  
19      controlled substance classified in Schedule II in an amount not to exceed a 72-hour supply for the  
20      patient in accordance with directions for use given by the dispensing practitioner only where the  
21      patient is not expected to require any additional amount of the controlled substance beyond the 72  
22      hours. Practitioners dispensing drugs pursuant to this subdivision shall meet the requirements of  
23      subdivision (f) of Section 11164.

24       “(c) Except as otherwise prohibited or limited by law, a practitioner specified in Section  
25      11150, may administer controlled substances in the regular practice of his or her profession.”

26       28. Health and Safety Code section 11164 states:

27       “Except as provided in Section 11167, no person shall prescribe a controlled substance, nor  
28      shall any person fill, compound, or dispense a prescription for a controlled substance, unless it

1 complies with the requirements of this section.

2       “(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V,  
3 except as authorized by subdivision (b), shall be made on a controlled substance prescription form  
4 as specified in Section 11162.1 and shall meet the following requirements:

5       “(1) The prescription shall be signed and dated by the prescriber in ink and shall contain the  
6 prescriber's address and telephone number; the name of the ultimate user or research subject, or  
7 contact information as determined by the Secretary of the United States Department of Health and  
8 Human Services; refill information, such as the number of refills ordered and whether the  
9 prescription is a first-time request or a refill; and the name, quantity, strength, and directions for  
10 use of the controlled substance prescribed.

11       “(2) The prescription shall also contain the address of the person for whom the controlled  
12 substance is prescribed. If the prescriber does not specify this address on the prescription, the  
13 pharmacist filling the prescription or an employee acting under the direction of the pharmacist  
14 shall write or type the address on the prescription or maintain this information in a readily  
15 retrievable form in the pharmacy.

16       “(b)(1) Notwithstanding paragraph (1) of subdivision (a) of Section 11162.1, any controlled  
17 substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically  
18 transmitted prescription, which shall be produced in hard copy form and signed and dated by the  
19 pharmacist filling the prescription or by any other person expressly authorized by provisions of  
20 the Business and Professions Code. Any person who transmits, maintains, or receives any  
21 electronically transmitted prescription shall ensure the security, integrity, authority, and  
22 confidentiality of the prescription.

23       “(2) The date of issue of the prescription and all the information required for a written  
24 prescription by subdivision (a) shall be included in the written record of the prescription; the  
25 pharmacist need not include the address, telephone number, license classification, or federal  
26 registry number of the prescriber or the address of the patient on the hard copy, if that information  
27 is readily retrievable in the pharmacy.

28       “(3) Pursuant to an authorization of the prescriber, any agent of the prescriber on behalf of

1 the prescriber may orally or electronically transmit a prescription for a controlled substance  
2 classified in Schedule III, IV, or V, if in these cases the written record of the prescription required  
3 by this subdivision specifies the name of the agent of the prescriber transmitting the prescription.

4 “(c) The use of commonly used abbreviations shall not invalidate an otherwise valid  
5 prescription.

6 “(d) Notwithstanding any provision of subdivisions (a) and (b), prescriptions for a  
7 controlled substance classified in Schedule V may be for more than one person in the same family  
8 with the same medical need.

9 “(e) This section shall become operative on January 1, 2005.”

10 29. Health and Safety Code section 11170 states:

11 “No person shall prescribe, administer, or furnish a controlled substance for himself.”

12 30. Health and Safety Code section 11171 states:

13 “No person shall prescribe, administer, or furnish a controlled substance except under the  
14 conditions and in the manner provided by this division.”

15 31. Health and Safety Code section 11190 states:

16 “(a) Every practitioner, other than a pharmacist, who prescribes or administers a controlled  
17 substance classified in Schedule II shall make a record that, as to the transaction, shows all of the  
18 following:

19 “(1) The name and address of the patient.

20 “(2) The date.

21 “(3) The character, including the name and strength, and quantity of controlled substances  
22 involved.

23 “(b) The prescriber’s record shall show the pathology and purpose for which the controlled  
24 substance was administered or prescribed.

25 “(c)(1) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled  
26 substance that is dispensed by a prescriber pursuant to Section 4170 of the Business and  
27 Professions Code, the prescriber shall record and maintain the following information:

28 “(A) Full name, address, and the telephone number of the ultimate user or research subject,

1 or contact information as determined by the Secretary of the United States Department of Health  
2 and Human Services, and the gender, and date of birth of the patient.

3 “(B) The prescriber’s category of licensure and license number; federal controlled substance  
4 registration number; and the state medical license number of any prescriber using the federal  
5 controlled substance registration number of a government-exempt facility.

6 “(C) NDC (National Drug Code) number of the controlled substance dispensed.

7 “(D) Quantity of the controlled substance dispensed.

8 “(E) ICD-9 (diagnosis code), if available.

9 “(F) Number of refills ordered.

10 “(G) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

11 “(H) Date of origin of the prescription.

12 “(2)(A) Each prescriber that dispenses controlled substances shall provide the Department  
13 of Justice the information required by this subdivision on a weekly basis in a format set by the  
14 Department of Justice pursuant to regulation.

15 “(B) The reporting requirement in this section shall not apply to the direct administration of  
16 a controlled substance to the body of an ultimate user.

17 “(d) This section shall become operative on January 1, 2005.

18 “(e) The reporting requirement in this section for Schedule IV controlled substances shall  
19 not apply to any of the following:

20 “(1) The dispensing of a controlled substance in a quantity limited to an amount adequate to  
21 treat the ultimate user involved for 48 hours or less.

22 “(2) The administration or dispensing of a controlled substance in accordance with any  
23 other exclusion identified by the United States Health and Human Service Secretary for the  
24 National All Schedules Prescription Electronic Reporting Act of 2005.

25 “(f) Notwithstanding paragraph (2) of subdivision (c), the reporting requirement of the  
26 information required by this section for a Schedule II or Schedule III controlled substance, in a  
27 format set by the Department of Justice pursuant to regulation, shall be on a monthly basis for all  
28 of the following:

1       “(1) The dispensing of a controlled substance in a quantity limited to an amount adequate to  
2 treat the ultimate user involved for 48 hours or less.

3       “(2) The administration or dispensing of a controlled substance in accordance with any  
4 other exclusion identified by the United States Health and Human Service Secretary for the  
5 National All Schedules Prescription Electronic Reporting Act of 2005.”

6       32. Health and Safety Code section 11191 states:

7       “The record shall be preserved for three years.

8       “Every person who violates any provision of this section is guilty of a misdemeanor.”

9       33. Health and Safety Code section 11747 states:

10       “(a) ‘Pharmaceutical’ means a prescription or over-the-counter human or veterinary drug,  
11 including, but not limited to, a drug as defined in Section 109925 or the Federal Food, Drug, and  
12 Cosmetic Act, as amended, (21 U.S.C.A. Sec. 321(g)(1)).

13       “(b) For purposes of this part, ‘pharmaceutical’ does not include any pharmaceutical that is  
14 regulated pursuant to either of the following:

15       “(1) The federal Resource Conservation and Recovery Act of 1976, as amended (42  
16 U.S.C.A. Sec. 6901 et seq.).”

17       “(2) The Radiation Control Law (Chapter 8 (commencing with Section 114960) of Part 9).

18       34. Health and Safety Code section 118275, subdivision (g) states:

19       “Biohazardous waste” means any of the following:

20       “...”

21       “(g) Waste that is hazardous only because it is comprised of pharmaceuticals, as defined in  
22 Section 117747. Notwithstanding subdivision (a) of Section 117690, medical waste includes  
23 biohazardous waste that meets the conditions of this subdivision. Biohazardous waste that meets  
24 the conditions of this subdivision is not subject to Chapter 6.5 (commencing with Section 25100)  
25 of Division 20.”

26       35. Health and Safety Code section 118275 states:

27       “To containerize or store medical waste, a person shall do all of the following:

28       “(a) Medical waste shall be contained separately from other waste at the point of origin in

1 the producing facility. Sharps containers may be placed in biohazard bags or in containers with  
2 biohazard bags.

3 “(b) Biohazardous waste, except biohazardous waste as defined in subdivision (g) of  
4 Section 117635, shall be placed in a red biohazard bag conspicuously labeled with the words  
5 “Biohazardous Waste” or with the international biohazard symbol and the word “BIOHAZARD.”

6 “(c) Sharps waste shall be contained in a sharps container pursuant to Section 118285.

7 “(d)(1) Biohazardous waste, which meets the conditions of subdivision (f) of Section  
8 117635 because it is contaminated through contact with, or having previously contained,  
9 chemotherapeutic agents, shall be segregated for storage, and, when placed in a secondary  
10 container, that container shall be labeled with the words “Chemotherapy Waste,” “CHEMO,” or  
11 other label approved by the department on the lid and on the sides, so as to be visible from any  
12 lateral direction, to ensure treatment of the biohazardous waste pursuant to Section 118222.

13 “(2) Biohazardous waste, which meets the conditions of subdivision (f) of Section 117635  
14 because it is comprised of human surgery specimens or tissues which have been fixed in  
15 formaldehyde or other fixatives, shall be segregated for storage and, when placed in a secondary  
16 container, that container shall be labeled with the words “Pathology Waste,” “PATH,” or other  
17 label approved by the department on the lid and on the sides, so as to be visible from any lateral  
18 direction, to ensure treatment of the biohazardous waste pursuant to Section 118222.

19 “(e) Sharps waste, which meets the conditions of subdivision (f) of Section 117635, shall be  
20 placed in sharps containers labeled in accordance with the industry standard with the words  
21 “Chemotherapy Waste,” “CHEMO,” or other label approved by the department, and segregated to  
22 ensure treatment of the sharps waste pursuant to Section 118222.

23 “(f) Biohazardous waste, which are recognizable human anatomical parts, as specified in  
24 Section 118220, shall be segregated for storage and, when placed in a secondary container for  
25 treatment as pathology waste, that container shall be labeled with the words “Pathology Waste,”  
26 “PATH,” or other label approved by the department on the lid and on the sides, so as to be visible  
27 from any lateral direction, to ensure treatment of the biohazardous waste pursuant to Section  
28 118222.

1       “(g) Biohazardous waste, which meets the conditions specified in subdivision (g) of Section  
2 117635, shall be segregated for storage and, when placed in a container or secondary container,  
3 that container shall be labeled with the words “INCINERATION ONLY” or other label approved  
4 by the department on the lid and on the sides, so as to be visible from any lateral direction, to  
5 ensure treatment of the biohazardous waste pursuant to Section 118222.

6       “(h) A person may consolidate into a common container, which may be reusable, sharps  
7 waste, as defined in Section 117755, and pharmaceutical wastes, as defined in Section 117747,  
8 provided that the consolidated waste is treated pursuant to paragraph (1) of subdivision (a) of  
9 Section 118215 and the container meets the requirements of Section 118285. The container shall  
10 be labeled with the biohazardous waste symbol and the words “HIGH HEAT ONLY,”  
11 “INCINERATION,” or other label approved by the department on the lid and on the sides, so as  
12 to be visible from any lateral direction, to ensure treatment of the biohazardous waste pursuant to  
13 this subdivision.”

#### 14                                   **CALIFORNIA REGULATIONS**

15       36. California Code of Regulations, title 16, section 1356.3 states:

16       “For purposes of section 4172 of the [C]ode, the phrase ‘area which is secure’ means a  
17 locked storage area within a physician’s office. The area shall be secure at all times. The keys to  
18 the locked storage area shall be available only to staff authorized by the physician to have access  
19 thereto.”

20       37. California Code of Regulations, title 16, section 1360 states:

21       “For the purposes of denial, suspension or revocation of a license, certificate or permit  
22 pursuant to Division 1.5 (commencing with Section 475) of the code, a crime or act shall be  
23 considered to be substantially related to the qualifications, functions or duties of a person holding  
24 a license, certificate or permit under the Medical Practice Act if to a substantial degree it  
25 evidences present or potential unfitness of a person holding a license, certificate or permit to  
26 perform the functions authorized by the license, certificate or permit in a manner consistent with  
27 the public health, safety or welfare. Such crimes or acts shall include but not be limited to the  
28 following: Violating or attempting to violate, directly or indirectly, or assisting in or abetting the

1 violation of, or conspiring to violate any provision of the Medical Practice Act.”

2 38. California Code of Regulations, title 16, section 1718, states:

3 “‘Current Inventory’ as used in Sections 4081 and 4332 of the Business and Professions  
4 Code shall be considered to include complete accountability for all dangerous drugs handled by  
5 every licensee enumerated in Sections 4081 and 4332.

6 “The controlled substances inventories required by Title 21, CFR, Section 1304 shall be  
7 available for inspection upon request for at least 3 years after the date of the inventory.”

#### 8 **FEDERAL STATUTES**

9 39. 21 U.S.C. section 802(2) and (10) states:

10 “(2) The term ‘administer’ refers to the direct application of a controlled substance to the  
11 body of a patient or research subject by--

12 “(A) a practitioner (or, in his presence, by his authorized agent), or

13 “(B) the patient or research subject at the direction and in the presence of the practitioner,  
14 “whether such application be by injection, inhalation, ingestion, or any other means.

15 “...”

16 “(10) The term ‘dispense’ means to deliver a controlled substance to an ultimate user or  
17 research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing  
18 and administering of a controlled substance and the packaging, labeling or compounding  
19 necessary to prepare the substance for such delivery. The term ‘dispenser’ means a practitioner  
20 who so delivers a controlled substance to an ultimate user or research subject.”

21 40. 21 U.S.C. section 827(b) states:

22 “Every inventory or other record required under this section (1) shall be in accordance with,  
23 and contain such relevant information as may be required by, regulations of the Attorney General,  
24 (2) shall (A) be maintained separately from all other records of the registrant, or (B) alternatively,  
25 in the case of nonnarcotic controlled substances, be in such form that information required by the  
26 Attorney General is readily retrievable from the ordinary business records of the registrant, and  
27 (3) shall be kept and be available, for at least two years, for inspection and copying by officers or  
28 employees of the United States authorized by the Attorney General.”

1 41. 21 U.S.C. section 842(a)(5) states:

2 "It shall be unlawful for any person--(5) to refuse or negligently fail to make, keep, or  
3 furnish any record, report, notification, declaration, order or order form, statement, invoice, or  
4 information required under this subchapter or subchapter II of this chapter. . . ."

5 **FEDERAL REGULATIONS**

6 42. Title 21, Code of Federal Regulations, section 1301.75(b) states:

7 "(b) Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely  
8 locked, substantially constructed cabinet. However, pharmacies and institutional practitioners  
9 may disperse such substances throughout the stock of noncontrolled substances in such a manner  
10 as to obstruct the theft or diversion of the controlled substances."

11 43. Title 21, Code of Federal Regulations, section 1304.03(a) states:

12 "(a) Each registrant shall maintain the records and inventories and shall file the reports  
13 required by this part, except as exempted by this section. Any registrant who is authorized to  
14 conduct other activities without being registered to conduct those activities, either pursuant to §  
15 1301.22(b) of this chapter or pursuant to §§ 1307.11–1307.13 of this chapter, shall maintain the  
16 records and inventories and shall file the reports required by this part for persons registered to  
17 conduct such activities. This latter requirement should not be construed as requiring stocks of  
18 controlled substances being used in various activities under one registration to be stored  
19 separately, nor that separate records are required for each activity. The intent of the  
20 Administration is to permit the registrant to keep one set of records which are adapted by the  
21 registrant to account for controlled substances used in any activity. Also, the Administration does  
22 not wish to require separate stocks of the same substance to be purchased and stored for separate  
23 activities. Otherwise, there is no advantage gained by permitting several activities under one  
24 registration. Thus, when a researcher manufactures a controlled item, he must keep a record of  
25 the quantity manufactured; when he distributes a quantity of the item, he must use and keep  
26 invoices or order forms to document the transfer; when he imports a substance, he keeps as part of  
27 his records the documentation required of an importer; and when substances are used in chemical  
28 analysis, he need not keep a record of this because such a record would not be required of him

1 under a registration to do chemical analysis. All of these records may be maintained in one  
2 consolidated record system. Similarly, the researcher may store all of his controlled items in one  
3 place, and every two years take inventory of all items on hand, regardless of whether the  
4 substances were manufactured by him, imported by him, or purchased domestically by him, of  
5 whether the substances will be administered to subjects, distributed to other researchers, or  
6 destroyed during chemical analysis."

7 "..."

8 "(d) A registered individual practitioner is not required to keep records of controlled  
9 substances listed in Schedules II, III, IV and V which are administered in the lawful course of  
10 professional practice unless the practitioner regularly engages in the dispensing or administering  
11 of controlled substances and charges patients, either separately or together with charges for other  
12 professional services, for substances so dispensed or administered. Records are required to be  
13 kept for controlled substances administered in the course of maintenance or detoxification  
14 treatment of an individual."

15 44. Title 21, Code of Federal Regulations, section 1304.04(a) states:

16 "(a) Except as provided in paragraphs (a)(1) and (a)(2) of this section, every inventory and  
17 other records required to be kept under this part must be kept by the registrant and be available,  
18 for at least 2 years from the date of such inventory or records, for inspection and copying by  
19 authorized employees of the Administration."

20 45. Title 21, Code of Federal Regulations, section 1304.11 states:

21 "(a) General requirements. Each inventory shall contain a complete and accurate record of  
22 all controlled substances on hand on the date the inventory is taken, and shall be maintained in  
23 written, typewritten, or printed form at the registered location. An inventory taken by use of an  
24 oral recording device must be promptly transcribed. Controlled substances shall be deemed to be  
25 'on hand' if they are in the possession of or under the control of the registrant, including  
26 substances returned by a customer, ordered by a customer but not yet invoiced, stored in a  
27 warehouse on behalf of the registrant, and substances in the possession of employees of the  
28 registrant and intended for distribution as complimentary samples. A separate inventory shall be

1 made for each registered location and each independent activity registered, except as provided in  
2 paragraph (e)(4) of this section. In the event controlled substances in the possession or under the  
3 control of the registrant are stored at a location for which he/she is not registered, the substances  
4 shall be included in the inventory of the registered location to which they are subject to control or  
5 to which the person possessing the substance is responsible. The inventory may be taken either as  
6 of opening of business or as of the close of business on the inventory date and it shall be indicated  
7 on the inventory.

8 “(b) Initial inventory date. Every person required to keep records shall take an inventory of  
9 all stocks of controlled substances on hand on the date he/she first engages in the manufacture,  
10 distribution, or dispensing of controlled substances, in accordance with paragraph (e) of this  
11 section as applicable. In the event a person commences business with no controlled substances on  
12 hand, he/she shall record this fact as the initial inventory.

13 “(c) Biennial inventory date. After the initial inventory is taken, the registrant shall take a  
14 new inventory of all stocks of controlled substances on hand at least every two years. The biennial  
15 inventory may be taken on any date which is within two years of the previous biennial inventory  
16 date.

17 “(d) Inventory date for newly controlled substances. On the effective date of a rule by the  
18 Administrator pursuant to §§ 1308.45, 1308.46, or 1308.47 of this chapter adding a substance to  
19 any schedule of controlled substances, which substance was, immediately prior to that date, not  
20 listed on any such schedule, every registrant required to keep records who possesses that  
21 substance shall take an inventory of all stocks of the substance on hand. Thereafter, such  
22 substance shall be included in each inventory made by the registrant pursuant to paragraph (c) of  
23 this section.

24 “(e) Inventories of manufacturers, distributors, dispensers, researchers, importers, exporters  
25 and chemical analysts. Each person registered or authorized (by § 1301.13 or §§ 1307.11–  
26 1307.13 of this chapter) to manufacture, distribute, dispense, import, export, conduct research or  
27 chemical analysis with controlled substances and required to keep records pursuant to § 1304.03  
28 shall include in the inventory the information listed below.

1       “(1) Inventories of manufacturers. Each person registered or authorized to manufacture  
2 controlled substances shall include the following information in the inventory:

3       “(i) For each controlled substance in bulk form to be used in (or capable of use in) the  
4 manufacture of the same or other controlled or non-controlled substances in finished form, the  
5 inventory shall include:

6       “(A) The name of the substance and

7       “(B) The total quantity of the substance to the nearest metric unit weight consistent with  
8 unit size.

9       “(ii) For each controlled substance in the process of manufacture on the inventory date, the  
10 inventory shall include:

11       “(A) The name of the substance;

12       “(B) The quantity of the substance in each batch and/or stage of manufacture, identified by  
13 the batch number or other appropriate identifying number; and

14       “(C) The physical form which the substance is to take upon completion of the  
15 manufacturing process (e.g., granulations, tablets, capsules, or solutions), identified by the batch  
16 number or other appropriate identifying number, and if possible the finished form of the substance  
17 (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the  
18 number or volume thereof.

19       “(iii) For each controlled substance in finished form the inventory shall include:

20       “(A) The name of the substance;

21       “(B) Each finished form of the substance (e.g., 10-milligram tablet or 10-milligram  
22 concentration per fluid ounce or milliliter);

23       “(C) The number of units or volume of each finished form in each commercial container  
24 (e.g., 100-tablet bottle or 3-milliliter vial); and

25       “(D) The number of commercial containers of each such finished form (e.g. four 100-tablet  
26 bottles or six 3-milliliter vials).

27       “(iv) For each controlled substance not included in paragraphs (e)(1) (i), (ii) or (iii) of this  
28 section (e.g., damaged, defective or impure substances awaiting disposal, substances held for

1 quality control purposes, or substances maintained for extemporaneous compoundings) the  
2 inventories shall include:

3 "(A) The name of the substance;

4 "(B) The total quantity of the substance to the nearest metric unit weight or the total number  
5 of units of finished form; and

6 "(C) The reason for the substance being maintained by the registrant and whether such  
7 substance is capable of use in the manufacture of any controlled substance in finished form.

8 "(2) Inventories of distributors. Except for reverse distributors covered by paragraph (e)(3)  
9 of this section, each person registered or authorized to distribute controlled substances shall  
10 include in the inventory the same information required of manufacturers pursuant to paragraphs  
11 (e)(1)(iii) and (iv) of this section.

12 "(3) Inventories of dispensers, researchers, and reverse distributors. Each person registered  
13 or authorized to dispense, conduct research, or act as a reverse distributor with controlled  
14 substances shall include in the inventory the same information required of manufacturers pursuant  
15 to paragraphs (e)(1)(iii) and (iv) of this section. In determining the number of units of each  
16 finished form of a controlled substance in a commercial container which has been opened, the  
17 dispenser, researcher, or reverse distributor shall do as follows:

18 "(i) If the substance is listed in Schedule I or II, make an exact count or measure of the  
19 contents, or

20 "(ii) If the substance is listed in Schedule III, IV or V, make an estimated count or measure  
21 of the contents, unless the container holds more than 1,000 tablets or capsules in which case  
22 he/she must make an exact count of the contents."

23 46. Title 21, Code of Federal Regulations, section 1304.21(a) states:

24 "(a) Every registrant required to keep records pursuant to § 1304.03 shall maintain on a  
25 current basis a complete and accurate record of each such substance manufactured, imported,  
26 received, sold, delivered, exported, or otherwise disposed of by him/her, except that no registrant  
27 shall be required to maintain a perpetual inventory."

28 47. Title 21, Code of Federal Regulations, section 1304.22(a) and (c) states:

1 "Each person registered or authorized (by § 1301.13(e) or §§ 1307.11–1307.13 of this  
2 chapter) to manufacture, distribute, dispense, import, export or conduct research with controlled  
3 substances shall maintain records with the information listed below.

4 "(a) Records for manufacturers. Each person registered or authorized to manufacture  
5 controlled substances shall maintain records with the following information:

6 "..."

7 "(2) For each controlled substance in finished form,

8 "(i) The name of the substance;

9 "(ii) Each finished form (e.g., 10–milligram tablet or 10–milligram concentration per fluid  
10 ounce or milliliter) and the number of units or volume of finished form in each commercial  
11 container (e.g., 100–tablet bottle or 3–milliliter vial);

12 "..."

13 "(iv) The number of units of finished forms and/or commercial containers acquired from  
14 other persons, including the date of and number of units and/or commercial containers in each  
15 acquisition to inventory and the name, address, and registration number of the person from whom  
16 the units were acquired;

17 "..."

18 "(vii) The number of commercial containers distributed to other persons, including the date  
19 of and number of containers in each reduction from inventory, and the name, address, and  
20 registration number of the person to whom the containers were distributed;

21 "..."

22 "(ix) The number of units of finished forms and/or commercial containers distributed or  
23 disposed of in any other manner by the registrant (e.g., by distribution of complimentary samples  
24 or by destruction), including the date and manner of distribution or disposal, the name, address,  
25 and registration number of the person to whom distributed, and the quantity in finished form  
26 distributed or disposed."

27 "..."

28 "(c) Records for dispensers and researchers. Each person registered or authorized to

1 dispense or conduct research with controlled substances shall maintain records with the same  
2 information required of manufacturers pursuant to paragraph (a)(2)(i), (ii), (iv), (vii), and (ix) of  
3 this section. In addition, records shall be maintained of the number of units or volume of such  
4 finished form dispensed, including the name and address of the person to whom it was dispensed,  
5 the date of dispensing, the number of units or volume dispensed, and the written or typewritten  
6 name or initials of the individual who dispensed or administered the substance on behalf of the  
7 dispenser. In addition to the requirements of this paragraph, practitioners dispensing gamma-  
8 hydroxybutyric acid under a prescription must also comply with § 1304.26.”

9 48. Title 21, Code of Federal Regulations, section 1305.03 states:

10 “Either a DEA Form 222 or its electronic equivalent as set forth in subpart C of this part  
11 and Part 1311 of this chapter is required for each distribution of a Schedule I or II controlled  
12 substance except for the following:

13 “(a) Distributions to persons exempted from registration under Part 1301 of this chapter.

14 “(b) Exports from the United States that conform with the requirements of the Act.

15 “(c) Deliveries to a registered analytical laboratory or its agent approved by DEA.

16 “(d) Delivery from a central fill pharmacy, as defined in § 1300.01 of this chapter, to a retail  
17 pharmacy.”

18 49. Title 21, Code of Federal Regulations, section 1305.04 states:

19 “(a) Only persons who are registered with DEA under section 303 of the Act (21 U.S.C.  
20 823) to handle Schedule I or II controlled substances, and persons who are registered with DEA  
21 under section 1008 of the Act (21 U.S.C. 958) to export these substances may obtain and use  
22 DEA Form 222 (order forms) or issue electronic orders for these substances. Persons not  
23 registered to handle Schedule I or II controlled substances and persons registered only to import  
24 controlled substances are not entitled to obtain Form 222 or issue electronic orders for these  
25 substances.

26 “(b) An order for Schedule I or II controlled substances may be executed only on behalf of  
27 the registrant named on the order and only if his or her registration for the substances being  
28 purchased has not expired or been revoked or suspended.”

1        50. Title 21, Code of Federal Regulations, section 1305.13(a) and (c) state:

2        “(a) A purchaser must submit Copy 1 and Copy 2 of the DEA Form 222 to the supplier and  
3 retain Copy 3 in the purchaser’s files.

4        “...”

5        “(c) The controlled substances must be shipped only to the purchaser and the location  
6 printed by the Administration on the DEA Form 222, except as specified in paragraph (f) of this  
7 section.”

8        51. Title 21, Code of Federal Regulations, section 1305.17 states:

9        “(a) The purchaser must retain Copy 3 of each executed DEA Form 222 and all copies of  
10 unaccepted or defective forms with each statement attached.

11        “(b) The supplier must retain Copy 1 of each DEA Form 222 that it has filled.

12        “(c) DEA Forms 222 must be maintained separately from all other records of the registrant.  
13 DEA Forms 222 are required to be kept available for inspection for a period of two years. If a  
14 purchaser has several registered locations, the purchaser must retain Copy 3 of the executed DEA  
15 Form 222 and any attached statements or other related documents (not including unexecuted DEA  
16 Forms 222, which may be kept elsewhere under § 1305.12(e)), at the registered location printed  
17 on the DEA Form 222.

18        “(d) The supplier of carfentanil, etorphine hydrochloride, and diprenorphine must maintain  
19 DEA Forms 222 for these substances separately from all other DEA Forms 222 and records  
20 required to be maintained by the registrant.”

21        52. Title 21, Code of Federal Regulations, section 1306.04(a) and (b) states:

22        “(a) A prescription for a controlled substance to be effective must be issued for a legitimate  
23 medical purpose by an individual practitioner acting in the usual course of his professional  
24 practice. The responsibility for the proper prescribing and dispensing of controlled substances is  
25 upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist  
26 who fills the prescription. An order purporting to be a prescription issued not in the usual course  
27 of professional treatment or in legitimate and authorized research is not a prescription within the  
28 meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling

1 such a purported prescription, as well as the person issuing it, shall be subject to the penalties  
2 provided for violations of the provisions of law relating to controlled substances.

3 “(b) A prescription may not be issued in order for an individual practitioner to obtain  
4 controlled substances for supplying the individual practitioner for the purpose of general  
5 dispensing to patients.”

6 53. Title 21, Code of Federal Regulations, section 1307.21 states:

7 “(a) Any person in possession of any controlled substance and desiring or required to  
8 dispose of such substance may request assistance from the Special Agent in Charge of the  
9 Administration in the area in which the person is located for authority and instructions to dispose  
10 of such substance. The request should be made as follows:

11 “(1) If the person is a registrant, he/she shall list the controlled substance or substances  
12 which he/she desires to dispose of on DEA Form 41, and submit three copies of that form to the  
13 Special Agent in Charge in his/her area; or

14 “(2) If the person is not a registrant, he/she shall submit to the Special Agent in Charge a  
15 letter stating:

16 “(i) The name and address of the person;

17 “(ii) The name and quantity of each controlled substance to be disposed of;

18 “(iii) How the applicant obtained the substance, if known; and

19 “(iv) The name, address, and registration number, if known, of the person who possessed  
20 the controlled substances prior to the applicant, if known.

21 “(b) The Special Agent in Charge shall authorize and instruct the applicant to dispose of the  
22 controlled substance in one of the following manners:

23 “(1) By transfer to person registered under the Act and authorized to possess the substance;

24 “(2) By delivery to an agent of the Administration or to the nearest office of the  
25 Administration;

26 “(3) By destruction in the presence of an agent of the Administration or other authorized  
27 person; or

28 “(4) By such other means as the Special Agent in Charge may determine to assure that the

1 substance does not become available to unauthorized persons.

2 “(c) In the event that a registrant is required regularly to dispose of controlled substances,  
3 the Special Agent in Charge may authorize the registrant to dispose of such substances, in  
4 accordance with paragraph (b) of this section, without prior approval of the Administration in  
5 each instance, on the condition that the registrant keep records of such disposals and file periodic  
6 reports with the Special Agent in Charge summarizing the disposals made by the registrant. In  
7 granting such authority, the Special Agent in Charge may place such conditions as he deems  
8 proper on the disposal of controlled substances, including the method of disposal and the  
9 frequency and detail of reports.

10 “(d) This section shall not be construed as affecting or altering in any way the disposal of  
11 controlled substances through procedures provided in laws and regulations adopted by any State.”

12 54. Title 21, Code of Federal Regulations, section 1300.01:

13 “Reverse distributor means a registrant who receives controlled substances acquired from  
14 another DEA registrant for the purpose of—

15 “(1) Returning unwanted, unusable, or outdated controlled substances to the manufacturer  
16 or the manufacturer’s agent; or

17 “(2) Where necessary, processing such substances or arranging for processing such  
18 substances for disposal.”

19 55. DEA, Definition and Registration of Reverse Distributors, 70 Fed. Reg. 22591, 22592  
20 (May 2, 2005) provides:

21 “The distributor, dispenser, or manufacturer may transfer the controlled substance to a  
22 reverse distributor to take custody of the controlled substances for the purpose of returning them  
23 to the manufacturer or arranging for their disposal.”

#### 24 CONTROLLED SUBSTANCE

25 56. Morphine is a Schedule II controlled substance as defined by 21 Code of Federal  
26 Regulations part 1308.12(b)(1)(ix) and California Health and Safety Code section 11055,  
27 subdivision (b)(1)(L). It is a dangerous drug as defined in California Business and Professions  
28 Code section 4022.

**FIRST CAUSE FOR DISCIPLINE**

**(Repeated Negligent Acts)**

57. Respondent is subject to disciplinary action under Code section 2234, subdivision (c), in that she engaged in repeated negligent acts with respect to the care and treatment of the Patient, a then 88-year-old female. The circumstances are as follows:

58. On or about July 30, 2014, Dr. A.A. (Doctor of Osteopathic Medicine) and P.M. (Respondent's business manager) made a house call visit to the Patient. At the time, Respondent was out of the country on vacation. Prior to leaving on vacation, she had arranged for Dr. A.A. to provide coverage from approximately July 22, 2014, to approximately August 8, 2014. Dr. A.A. was in her eighth month of pregnancy.

59. Dr. A.A. performed a history and conducted a physical examination of the Patient. Her assessment was right lower extremity with slight edema. Her plan and orders included a Doppler study to rule out Deep Vein Thrombosis of the right lower extremity, an x-ray of the right hip and pelvis to rule out occult fracture, and Morphine 4 mg one hour prior to the Doppler study due to severe pain. The progress note mistakenly identifies Respondent as the physician who examined the Patient.

60. On or about July 30, 2014, Respondent maintained a supply of Morphine in a locked safe. She obtained the supply by writing a prescription on or about February 24, 2014, and on or about July 4, 2014, for Morphine Sulfate 10 mg/ml injectable, quantity 25, "for office use" in order to administer, dispense, or furnish the controlled substance to patients. Respondent's business manager, P.M., had access to the safe and its contents, including the Morphine. Respondent did not maintain a drug log reflecting to whom the Morphine was administered and other information required by law.

61. The next day, on or about July 31, 2014, P.M. had unsupervised access to a 10 mg vial of Morphine. He transported the Morphine from the safe to the Patient's home. Dr. A.A. was not present during the house call visit because she was tired. Per Dr. A.A.'s order and instruction, P.M. administered 4 mg of Morphine into the Patient's arm. Approximately 15-30 minutes after the administration of the Morphine, the Patient had a cardiovascular arrest. The

1 Patient subsequently died.

2 62. P.M. was acting as a medical assistant when in fact he is not a trained medical  
3 assistant as defined by Business and Professions Code section 2069, subdivision (b)(1). He did  
4 not have equipment for cardiopulmonary resuscitation (CPR) or basic life support at the time of  
5 the injection. A licensed provider or supervisor was not present to verify the correct dosage or  
6 supervise his administration of the Morphine as required by Business and Professions Code  
7 section 2069, subdivisions (a)(1) and (b)(3)(A). When he was unable to arrange for a trained  
8 medical person to administer the Morphine, P.M. watched a "You Tube" video and administered  
9 the Morphine himself.

10 63. The progress note for July 31, 2014, mistakenly identifies Respondent as being  
11 present during the encounter. However, at the time, Respondent was in a remote area, on safari.  
12 She responded (via a series of text messages with P.M.) that she did not generally approve of him  
13 administering the Morphine, but that it was okay this time.

14 64. As stated above, Respondent's medical records for the Patient dated July 30, 2014,  
15 and July 31, 2014, inaccurately reflect that Respondent provided care and treatment to the Patient  
16 on those dates even though she was not physically present during the visits. In addition, narcotics  
17 were ordered under Respondent's name in the medical record even though she did not perform a  
18 history or examination of the Patient.

19 65. Under Title 21, Code of Federal Regulations, sections 1306.04(a) and (b), and  
20 California Health and Safety Code sections 11153(a), 11158, 11164, 11170, and 11171, a  
21 physician is prohibited from issuing a prescription in order to obtain a supply of controlled  
22 substances for the purpose of general dispensing to patients. A DEA registered physician who has  
23 a need for Schedule II controlled substances for office or medical bag use must obtain these drugs  
24 by completing a federal order (form DEA-222) as required by Title 21, Code of Federal  
25 Regulations, sections 1305.03, 1305.04, 1305.13(a) and (c), and 1305.17.

26 66. From on or about February 24, 2014, to on or about July 31, 2014, Respondent  
27 furnished, dispensed, or administered controlled substances to patients without record keeping  
28 required by 21 U.S.C. sections 842(a)(5) and 827(b), Title 21, Code of Federal Regulations,

1 sections 1304.03(a) and (d), 1304.21(a), 1304.22(c), and California Health and Safety Code  
2 sections 11190 and 11191.

3 67. From on or about February 24, 2014, to on or about July 31, 2014, Respondent failed  
4 to maintain a drug log showing the number of units or volume of Morphine furnished, including  
5 the name and address of the person to whom it was dispensed, the date of dispensing, the number  
6 of units or volume dispensed, and the written or typewritten name or initials of the individual who  
7 dispensed or administered the substance on behalf of the dispenser. The records must either be  
8 maintained separately from all other records or be in such form that the required information is  
9 readily retrievable from the ordinary business records of Respondent. The foregoing is in  
10 violation of 21 U.S.C. 827(b), Title 21 Code of Federal Regulations, section 1304.22(c), and  
11 California Health and Safety Code sections 11190 and 11191.

12 68. Under 21 U.S.C. section 827(b) and Title 21, Code of Federal Regulations, sections  
13 1304.03(a) and (d), 1304.04(a), 1304.11, a physician must take an initial inventory, which is an  
14 actual physical count of all controlled substances in his or her possession. Physicians who  
15 frequently dispense drugs are required to take an inventory every two years of all controlled  
16 substances on hand. The records must be maintained on file for at least two years. Under  
17 Business and Professions Code sections 4080 and 4081, subdivision (a), a current inventory of  
18 dangerous drugs and dangerous devices must be made and kept for at least three years by every  
19 physician who maintains a stock of dangerous drugs or dangerous devices. From on or about  
20 February 24, 2014, to on or about July 31, 2014, Respondent failed to maintain an inventory of  
21 the Morphine.

22 69. A physician who stores controlled substances in the office or clinic is required to keep  
23 them in a securely locked and substantially constructed cabinet or safe pursuant to Business and  
24 Professions Code sections 4170 and 4172 and Title 21, Code of Federal Regulations, section  
25 1301.75(b). P.M. had unsupervised access to narcotic medications and transported them to the  
26 Patient.

27 70. Syringes and partially used drugs should be disposed of in a manner which precludes  
28 them from being used again and complies with laws pertaining to the proper disposal of

1 biohazardous waste under Business and Professions Code section 4119, California Health and  
2 Safety Code section 118275, Title 21, Code of Federal Regulations, sections 1300.01 and  
3 1307.21, and DEA, Definition and Registration of Reverse Distributors, 70 Fed. Reg. 22591,  
4 22592 (May 2, 2005). There is no indication that Respondent had a policy for the safe disposal of  
5 partially used Morphine vials.

6 71. Respondent's failure to adhere to the guidelines for the purchase, use of order forms,  
7 inventory, record keeping, storage, security, administration, and safe disposal of controlled  
8 substances is a departure from the standard of care.

9 72. Respondent's response (regardless of whether it was sent before or after the Morphine  
10 injection) that it was okay to administer Morphine by an untrained person is a departure from the  
11 standard of care. There was no emergent need to administer Morphine. Administering Morphine  
12 by an untrained person unnecessarily increases the risk of complication.

13 73. Respondent's failure to arrange a backup plan in the event that Dr. A.A. was unable to  
14 carry out her professional duties is a departure from the standard of care. Respondent did not  
15 have a backup plan for the possibility that Dr. A.A. might become unable to carry out her duties.  
16 It is known that women in the eighth month of pregnancy will deliver before the expected due  
17 date, or have other pregnancy-related complications. After Dr. A.A. ordered Morphine, the  
18 responsibility for finding a provider to administer the injection was turned over to P.M., the  
19 business manager. Respondent's arrangement for coverage was inadequate.

20 74. Respondent's acts and/or omissions as set forth in paragraphs 58 through 73,  
21 inclusive above, whether proven individually, jointly, or in any combination thereof, constitute  
22 repeated negligent acts pursuant to Code section 2234, subdivision (c). Therefore, cause for  
23 discipline exists.

## 24 **SECOND CAUSE FOR DISCIPLINE**

### 25 **(Violation of State and Federal Regulation of Drugs)**

26 75. Respondent is subject to disciplinary action under Code section 2238 in that she  
27 violated federal and state statutes and regulations regulating dangerous drugs or controlled  
28 substances. The circumstances are as follows:

1       76. The facts and circumstances are as set forth in paragraphs 58 through 73 above, and  
2 are incorporated by reference.

3       77. Respondent's acts and/or omissions as set forth in paragraphs 58 through 73,  
4 inclusive above, whether proven individually, jointly, or in any combination thereof, constitute a  
5 violation of federal and state statutes and regulations regulating dangerous drugs or controlled  
6 substances pursuant to Code section 2238. Therefore, cause for discipline exists.

7                               **THIRD CAUSE FOR DISCIPLINE**

8                               **(Inadequate and Inaccurate Recordkeeping)**

9       78. Respondent is subject to disciplinary action under Code section 2266 in that she failed  
10 to maintain adequate and accurate records. The circumstances are as follows:

11       79. The facts and circumstances are as set forth in paragraphs 58 through 73 above, and  
12 are incorporated by reference.

13       80. Respondent's acts and/or omissions as set forth in paragraphs 58 through 73,  
14 inclusive above, whether proven individually, jointly, or in any combination thereof, constitute  
15 inadequate and inaccurate records pursuant to Code section 2266. Therefore, cause for discipline  
16 exists.

17                               **FOURTH CAUSE FOR DISCIPLINE**

18                               **(Aiding and Abetting the Unlicensed Practice of Medicine)**

19       81. Respondent is subject to disciplinary action under Code sections 2051, 2052, 2053.5,  
20 2234, subdivision (a), and 2264 and California Code of Regulations, title 16, section 1360 in that  
21 she aided and abetted the unlicensed practice of medicine by P.M., a layperson. The  
22 circumstances are as follows:

23       82. The facts and circumstances are as set forth in paragraphs 58 through 73 above, and  
24 are incorporated by reference.

25       83. Respondent's acts and/or omissions as set forth in paragraphs 58 through 73,  
26 inclusive above, whether proven individually, jointly, or in any combination thereof, constitute  
27 aiding and abetting the unlicensed practice of medicine pursuant to sections 2051, 2052, 2053.5,  
28 2234, subdivision (a), and 2264 of the Code and California Code of Regulations, title 16, section

1 1360. Therefore, cause for discipline exists.

2 **FIFTH CAUSE FOR DISCIPLINE**

3 **(Unprofessional Conduct)**

4 84. Respondent is subject to disciplinary action under Code section 2234 for  
5 unprofessional conduct. The circumstances are as follows:

6 85. The facts and circumstances are as set forth in paragraphs 58 through 83 above, and  
7 are incorporated by reference.

8 86. Respondent's acts and/or omissions as set forth in paragraphs 58 through 83,  
9 inclusive above, whether proven individually, jointly, or in any combination thereof, constitute  
10 unprofessional conduct pursuant to Code section 2234. Therefore, cause for discipline exists.

11 **PRAYER**

12 WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,  
13 and that following the hearing, the Medical Board of California issue a decision:

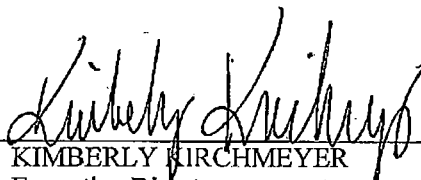
14 1. Revoking or suspending Physician's and Surgeon's Certificate Number G 89024,  
15 issued to Respondent Ellen B. Crowe, M.D.;

16 2. Revoking, suspending or denying approval of Respondent Ellen B. Crowe, M.D.'s  
17 authority to supervise physician assistants and advanced practice nurses;

18 3. Ordering Respondent Ellen B. Crowe, M.D., if placed on probation, to pay the Board  
19 the costs of probation monitoring; and

20 4. Taking such other and further action as deemed necessary and proper.

21  
22  
23 DATED: May 17, 2018

  
KIMBERLY KIRCHMEYER  
Executive Director  
Medical Board of California  
Department of Consumer Affairs  
State of California  
Complainant

24  
25  
26  
27  
28 LA2018501123  
52903201.docx